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#4  
INTER-SPINOUS PROCESS IMPLANT AND METHOD  
WITH DEFORMABLE SPACER

Inventors:

5 James F. Zucherman  
Ken Y. Hsu  
Charles J. Winslow  
John Flynn

10 Claim of Priority

[0001] This application claims priority to United States Provisional Patent Application entitled INTER-SPINOUS PROCESS IMPLANT AND METHOD WITH DEFORMABLE SPACER, filed September 18, 2001, Serial No. 60/323,467 and is a continuation-in-part of U.S. Patent Application Serial No. 09/799,215 filed on March 5, 15 2001, entitled SPINAL IMPLANTS, INSERTION INSTRUMENTS, AND METHOD OF USE, which is a continuation-in-part of U.S. Patent Application Serial No. 09/473,173 filed on December 28, 1999, entitled SPINE DISTRACTION IMPLANT, now U.S. Patent No. 6,235,030 issued on May 22, 2001, which is a continuation of U.S. Patent Application Serial No. 09/179,570 filed on October 27, 1998, entitled SPINE 20 DISTRACTION IMPLANT, now U.S. Patent No. 6,048,342 issued on April 11, 2000, which is a continuation-in-part of U.S. Patent Application No. 09/474,037 filed on December 28, 1999 and entitled SPINE DISTRACTION IMPLANT, now U.S. Patent No. 6,190,387, issued February 20, 2001, which is a continuation of U.S. Patent Application Serial No. 09/175,645 filed on October 20, 1998, entitled SPINE

DISTRACTION IMPLANT, now U.S. Patent No. 6,068,630 issued on May 30, 2000.

All of the above are incorporated herein by reference.

Field of the Invention

5 [0002] The present invention is generally related to an implantable device adapted to distract the spinous process of adjacent vertebrae in order to alleviate the back pain caused by, for example, spinal stenosis and other ailments.

Background of the Invention

10 [0003] The vertebral column is a bio-mechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The bio-mechanical functions of the spine include (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts and (3) protection of the spinal cord and the nerve roots.

15 [0004] As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. By way of example, with aging comes increases in spinal stenosis (including but not limited to central canal and lateral stenosis), the thickening of the bones which make up the spinal column, and the facet arthropathy. Spinal stenosis is characterized by a reduction in the available space for the passage of blood vessels and nerves. Pain associated with such stenosis can be relieved by

medication and/or surgery. Of course, it desirable to eliminate the need for major surgery for all individuals and in particular for the elderly.

5 [0005] In addition, there are a variety of other ailments that can cause back pain in patients of all ages. For these ailments it is also desirable to eliminate such pain without major surgery.

[0006] Accordingly, there needs to be developed implants for alleviating such conditions which are minimally invasive, can be tolerated by patients of all ages and in particular the elderly, and can be performed preferably on an out patient basis.

10 Summary of the Invention

[0007] The present invention is directed to providing a minimally invasive implant for alleviating discomfort associated with the spinal column.

[0008] In one aspect of the present invention, the implant reduces and/or eliminates pain by relieving the pressure and restrictions on the aforementioned blood vessels and nerves. Such alleviation of pressure is accomplished by an implant which distracts the spinous processes in order to alleviate the problems caused by spinal stenosis, facet arthropathy and other spinal ailments. While the implant particularly addresses the needs of the elderly, embodiments of the invention can be used with individuals of all ages and sizes where distraction of the spinous processes and/or the maintenance of a spacing between the spinous processes would be beneficial.

[0009] Another aspect of the present invention includes an implant with a first support and a second support, having a compressible medium between the first and second support. The compressible medium preferably progressively limits the motion of the adjacent spinous process. The first and second support have a saddle for engaging each spinous process.

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[0010] Yet another aspect of an embodiment of the present invention is a spacer adapted to be compressed in reaction to forces from a spinous process placed upon the spacer. The spacer has a compressible medium that provides resistance against compression. Such a flexible spacer provides an individual with a larger range of motion.

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[0011] It is still another aspect of an embodiment of the present invention to include a compressible spacer which prevents wear debris.

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[0012] Other implants and embodiments within the spirit and scope of the invention can be used to distract the spinous processes, to maintain the distance between the spinous processes and/or to increase the volume of the spinal canal, thereby alleviating restrictions on vessels and nerves associated therewith, and/or pain.

#### Brief Description of the Drawings

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[0013] Figures 1a-1g; Fig. 1a is an assembly view of an embodiment of the invention; Fig. 1b is a side view of the embodiment of the invention of Fig. 1a including a spacer, a main body and a first wing; Fig. 1c is a plane view of the embodiment of the invention in Fig. 1b; Fig. 1d is a side view illustrating the second wing of the embodiment of

the invention in Fig. 1a; Fig. 1e is a plane view of the second wing of an embodiment of the invention of Fig. 1a; Fig. 1f is an end view of the spacer of the embodiment of the invention of Fig. 1a; Fig. 1g is a cut-away view illustrating the spacer of the embodiment of the invention of Fig. 1a.

5 [0014] Figure 2 is a perspective view of still another embodiment of the spacer of the invention;

[0015] Figure 3 is a perspective view of yet another embodiment of the spacer of the invention;

10 [0016] Figure 4 is a perspective view of still another embodiment of the spacer of the invention;

[0017] Figures 5a-5b; Figure 5a is a perspective view of yet another embodiment of the spacer of the invention; Figure 5b is an end view of the embodiment of the spacer illustrated in Figure 5a;

15 [0018] Figures 6a-6c; Figure 6a is a perspective view of yet another embodiment of the spacer of the invention; Figure 6b is a perspective view of the first outer shell of the spacer illustrated in Figure 6a; Figure 6c is an end view of the embodiment of the spacer shown in Figure 6a filled with a deformable or compressible material;

[0019] Figure 7 is a perspective view of yet another embodiment of the spacer of the invention;

20 [0020] Figures 8a-8b are perspective views of still other embodiments of the spacer of the invention; and

[0021] Figures 9a-9b; Fig. 9a is a perspective view of another embodiment of the present invention; Fig. 9b is a cut-away view of the embodiment of the invention illustrated in Fig. 9a.

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Detailed Description of the Invention

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[0022] An embodiment of the implant **100** is depicted in Figs. 1a, 1b and 1c. This implant includes the first wing **104** and sleeve **116** and a lead-in and distraction guide **110**. This embodiment further includes, as required, a second wing **132** as depicted in Figs. 1d and 1e. As can be seen in Fig. 1a, a central body **102** extends from the first wing **104**. Also, as can be seen in Figs. 1a and 1b, the guide **110** in this particular embodiment is pointed in order to allow the implant to be inserted between, and if necessary distract, adjacent spinous processes.

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[0023] Additionally, As can be seen in Figs. 1a, 1f and 1g, the sleeve **116** is preferably cylindrical, and oval or elliptical in shape in cross-section. It is to be understood that sleeve **116** can have other shapes as described throughout the specification and be within the spirit and scope of the invention. Sleeve **116** includes a central bore **119** which extends the length of sleeve **116**. The sleeve **116** is received over the central body **102** of the implant **100** and can rotate thereon about the central body **102**. In these embodiments, the spacer **116** can preferably have minor and major dimensions as follows:

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	<u>Minor Dimension (116a)</u>	<u>Major Dimension (116b)</u>
5	6 mm	10 mm
	8 mm	10.75 mm
	12 mm	14 mm
	6 mm	12.5 mm
	8 mm	12.5 mm
	10 mm	12.5 mm

[0024] In another preferred embodiment, the spacer 116 has a cross-section with a major dimension and a minor dimension and the major dimension is greater than the minor dimension and less than about two times the minor dimension.

[0025] It is to be understood that the sleeve can be comprised of biologically acceptable material such as titanium or stainless steel. Additionally, it can be comprised of super-elastic material such as an alloy of nickel and titanium. Other structural and material variations for the sleeve are described below.

15 [0026] The advantage of the use of the sleeve 116 as depicted in the embodiment of Figs. 1a is that the sleeve can be rotated and repositioned with respect to the first wing 104, in the embodiment, in order to more optimally position the implant 100 between spinous processes. It is to be understood that the cortical bone or the outer shell of the spinous processes is stronger at an anterior position adjacent to the vertebral bodies of the 20 vertebra than at a posterior position distally located from the vertebral bodies. Accordingly, there is some advantage of having the implant 100 placed as close to the vertebral bodies as is possible. In order to facilitate this and to accommodate the anatomical form of the

bone structures, as the implant is inserted between the vertebral bodies and urged toward the vertebral bodies, the sleeve 116 can be rotated relative to the wings, such as wing 104, so that the sleeve is optimally positioned between the spinous processes, and the wing 104 is optimally positioned relative to the spinous processes. Without this capability, depending 5 on the anatomical form of the bones, it is possible for the wings to become somewhat less than optimally positioned relative to the spinous processes.

[0027] As required, the implant 100 can also include a second wing 132 which fits over the guide 110 and is preferably secured by a bolt through apparatus 134 of second wing 132 to the threaded bore 112 located in guide 110. As implanted, the first wing 104 is located next to the adjacent first side of the spinous processes and the second wing 132 10 is located adjacent to second side of the same spinous processes.

[0028] Referring now to Figures 2-8, various embodiments of spacers adapted for placing between the first wing 104 and the second wing 132 are shown. The preferred material for the various spacers described below is titanium in combination with a 15 deformable material such as silicone. It is within the scope of the present invention to manufacture the spacers from other biologically acceptable material such as, by way of example only, stainless steel or an alloy of nickel and titanium along with another deformable material such as another deformable polymer.

[0029] Turning now to Figure 2, the spacer 200 includes an outer shell 202. The 20 outer shell 202 is integrally formed with the center shaft 206 by two support columns 204. The center shaft has a bore 208 extending through. Each support column 204 extends

substantially perpendicular from the center shaft 206. Between the outer shell 202 and the center shaft 206, a cavity 205 is created.

[0030] The shape of the outer shell 202 as shown in Figure 2 is elliptical in shape.

It is within the scope of the invention that the outer shell 202 may comprise other shapes

5 such as, but not limited to, a cylindrical or egg shape. Regardless of the shape, the outer

shell 202 is not continuous in this preferred embodiment. One half of the outer shell 202

extends from the end of one support column 204a and around the center shaft 206 until the

outer shell 202 almost reaches the second support column 204b. The second half of the

outer shell 202 is the same as the first half, and in this case both halves extend in a clockwise

10 direction. Since each half of the outer shell 202 extends from a different support column

204, two slots 210a and 210b are created. Both slots 210a,b extend along the length of

the spacer 200. The slots 210 function to lower the rigidity of the outer shell 202 so that the

outer shell 202 is more flexible and functions as a cantilever spring. The smallest diameter

of the space (circular or elliptical) can preferably range from 6 mm. to 11 mm. The

15 thickness of the outer shell can preferably be 2 mm. The spacer can have other dimensions

as identified previously.

[0031] Preferably, a compressible substance 207 is placed into the cavities 205a,b

located between the outer shell 202 and the center shaft 206. The compressible substance

207 provides resistance against the outer shell 202 traveling towards the center shaft 206.

20 As previously mentioned, the compressible substance in this embodiment is preferably

silicone. It is within the scope of the invention that the compressible substance 207 may

comprise another medium such as, but not limited to, urethane-coated silicone and/or co-formed with silicone so that the urethane will not be attacked by the body, or another ultra-high molecular weight polymer. Another preferred material is polycarbonate-urethane, a thermoplastic elastomer formed as the reaction product of a hydroxyl terminated polycarbonate, an aromatic diisocyanate, and a low molecular weight glycol used as a chain extender. A preferred polycarbonate glycol intermediate, poly (1,6-hexyl 1,2-ethyl carbonate) diol, PHECD, is the condensation product of 1,6-hexanediol with cyclic ethylene carbonate. The polycarbonate macroglycol is reacted with aromatic isocyanate, 4, 4'-methylene bisphenyl diisocyanate (MDI), and chain extended with 1, 4-butanediol. This material is preferable used at a hardness of 55 durometer. This material, as well as the other materials, can be used in the other embodiments of the invention.

10 [0032] The compressible medium preferably has a graduated stiffness to help gradually distribute the load when a spinous processes places a force upon the outer shell 202. For example, the hardness of the silicone can be the lowest where the silicone contacts the outer shell 202, and the hardness of the silicone can be the highest where the silicone contacts the center shaft 206. Alternatively, the silicone can have a higher hardness in the center of the silicone located between the outer shell 202 and the center shaft 206.

15 [0033] The compressible medium 207 fills the cavity between the outer shell 202 and the center shaft 206 and is flush with the outer shell 202. When the spacer 200 is inserted between adjacent spinous processes, the outer shell 202 protects the compressible substance (e.g., silicone) from directly contacting the spinous processes because the slots

210 are along the side of the spacer 200. Therefore, the deformable material 207 does contact the spinous processes and wear debris is reduced or eliminated.

[0034] It is to be understood that for this and also in the embodiments in Figures 3, 5a and 5b, the embodiment can be constructed without a compressible material, with the outer shell solely providing the flexibility of the spacer. It is also to be understood that the 5 embodiments shown in Figures 3 - 8 can have the dimensions and be made of the materials similar to those of Figure 2. It is additionally to be understood that the metal components of any of the embodiments hereof can be comprised of a suitable plastic or composite material including fibers for strength.

10 [0035] Now referring to Figure 3, the spacer 300 has an outer shell 302 and a center shaft 306. The center shaft 306 has a bore 308 extending through. The center shaft 306 is connected with the outer shell 302 by two support columns 304a,b, with each support column 304a,b located on opposite sides of the center shaft 306. Similar to the embodiment of the present invention as illustrated in Figure 2, the outer shell 302 is elliptical, yet may comprise other shapes such as , but not limited to, a cylindrical or egg shape.

15 [0036] The outer shell 302 has two slots 310a,b. The slots 310a,b extend through the wall of the outer shell 302 to form a rectangular-like opening. It is within the scope of the invention for the spacer 300 to have more than two slots 310 and with different shapes. The slots 310a,b are used to make the outer shell 302 more flexible. It is preferred that the 20 slots 310a,b are located on the sides of the spacer 300 so that none of the slots 310a,b contact a spinous process.

[0037] Between the outer shell 302 and the center shaft 306 are two cavities 305a,b. These cavities are separated by the support columns 304a,b. The two cavities created between the outer shell 302 and the center shaft 306 preferably have a compressible substance therein. As previously mentioned, the compressible substance is preferably 5 silicone. To improve the load distribution upon the outer shell 302 and ease the load on the spinous processes, the silicone can have a graduated stiffness. For example, the hardness of the silicone can be the lowest where the outer shell 302 contacts the silicone, and the hardness of the silicone can be the highest where the center shaft 306 and the support column 304 contacts the silicone. Alternatively, the silicone can have a higher hardness in 10 the center of the silicone riding between the outer shell 302 and the center shaft 306.

[0038] The silicone is placed between the outer shell 302 and the center shaft 306 so that the silicone extends into the slots 310 and is flush with the outer shell 302. Since the spinous processes do not directly contact the silicone, this embodiment of the present invention also helps prevent wear debris.

[0039] Referring now to Figure 4, yet another embodiment of the present invention includes spacer 400. The spacer 400 has an outer shell 402 and a center shaft 406. The center shaft 406 has a bore 408 extending through. The spacer 400 has two openings 410a,b that are substantially along the top 111 and bottom 113 portions of the outer shell 402. Between the outer shell 402 and the center shaft 406, cavities 405a,b are created 20 which connects the two openings 410a,b.

[0040] Similar to the previous embodiments, a compressible medium such as silicone is placed into the cavity **405a,b** and openings **410a,b** until the silicone becomes flush with the outer shell **402**. Preferably, the silicone also has a graduated stiffness. For example, the hardness of the silicone can be the lowest where it is flush with the outer shell **402**, and can be the highest where the silicone contacts the center shaft **406**. Unlike the previous embodiments, the exposed silicone will directly contact the spinous processes.

[0041] Referring now to Figures 5a-5b, another embodiment of the invention is spacer **500**. The spacer **500** has an outer shell **502** and a center shaft **506**. The outer shell **502** forms a “C”-like shape. The center shaft **506** has a bore **508** extending through. The center shaft **506** is attached to the outer shell **502** by a support **504**. The support **504** is substantially horizontal extending from the vertical center of the “C” to the middle of the open end **509**. The outer shell **502** defines two slots **510a,b** along the length of the open end **509**. Both slots **510a,b** are defined by the space between the support **504** and each end portion of the outer shell **502**. Since the outer shell **502** is fixed at one end only, the outer shell **502** functions like a cantilever-type spring. The outer shell **502** is shown as elliptical in shape. It is within the scope of the present invention that the spacer **500** may comprise other shapes such as, but not limited to, a cylindrical or egg shape.

[0042] The support **504** has preferably at least two protrusions such as protrusions selected from protrusions **512a,b,c,d**. For example, the spacer **500** in Figures 5a,b has four protrusions **512a,b,c,d**. Each protrusion **512a,b,c,d** extends substantially and preferably perpendicular in this embodiment from the support **504** towards the inner surface of the

outer shell **502**. While the spacer **500** is in a non-compressed state, there is a gap between each protrusion **512a,b,c,d** and the outer shell **502**. When the spacer **500** is compressed, the protrusions **512a,b,c,d** function to restrict the deflection of the outer shell **502**. When a spinous process exerts a force upon the outer shell **502**, the outer shell **502** will deflect 5 toward the center shaft **506** until the outer shell **502** contacts the protrusion **512a,b,c,d**. Essentially, the protrusions **512a,b,c,d**, function as a stop mechanism preventing the outer shell **502** from deflecting too much, and thus limiting the motion of the spinous processes.

10 [0043] Similar to the previous embodiments, cavities **505a,b** are formed between the center shaft **506** and the outer shell **502**. A compressible substance such as silicone is placed within the cavity **505**. It is preferable that the silicone have a graduated stiffness to help distribute the load placed upon the outer shell **502**. For example, the hardness of the 15 silicone can be the lowest where the silicone contacts the inner surface of the outer shell **502**, and the hardness of the silicone can be the highest where the silicone contacts the center support shaft **506**, and the support **504** and the protrusions **512a,b,c,d**. Alternatively, the silicone can have a higher hardness in the center of the silicone rising between the outer shell **502** and the center shaft **506**.

20 [0044] The silicone fills the cavities **505a,b** until the silicone is flush with the outer shell **502**. When the spacer **500** is inserted between adjacent spinous processes, the top and bottom portions **514, 516** of the spacer **500** contact the spinous process. Therefore, the silicone will not directly contact the spinous processes which aids in the prevention of 25 wear debris.

[0045] Referring now to Figures 6a-6c, another embodiment of the present invention is spacer 600. The spacer 600 has a first outer shell 602 and a second outer shell 603. The first outer shell 602 has at least two support elements 604a,b. Each support element 604a,b has a bore 605a,b extending therethrough. The support elements 604a,b are located substantially at either end of the first outer shell 602 along a single horizontal axis. The bores 605a,b are oval in a preferred embodiment. This shape allows the spacer 600 to move relative to the central shaft or axis (Figure 1) upon which the spacer is mounted. The second outer shell 603 has a single support element 606, located substantially in the center of the second outer shell 603 and along the same horizontal axis as the two support elements 604a,b. The support element 606 also has a bore extending through which is similar to bore 605. Support element 606 is located between support element 604a,b in Fig.6a. A central shaft 612 (shaft 102 in Fig. 1c) is placed through the support elements 604a,b, 606 to form a hinge-type connection between the first outer shell 602 and the second outer shell 603 (see Figure 6a). The hinge-type connection allows the first outer shell 602 and the second outer shell 603 to move independently of each other.

[0046] When the first outer shell 602 and the second outer shell 603 are connected by shaft 612, slots 610a,b are created along the side edges of the spacer 600. Two cavities 614a,b are also created, defined by the hinge-type connection between the first outer shell 602 and the second outer shell 603. Similar to the previous embodiments, a compressible substance (e.g., silicone) can fill each cavity and extend into the slots 610a,b until the silicone is flush with the first outer shell 602 and the second outer shell 603. Additionally, it is

preferred that the silicone have a graduate hardness similar to the previous embodiments.

In one embodiment, the hardness of the silicone can be the highest along view line A-A, and can be the lowest where the silicone contacts the first and second outer shell 602, 603.

Alternatively, the silicone can have the highest hardness where it contacts the support

5 elements 604a,b, 606, and can have the lowest hardness where the silicone fills the slots 610a,b.

[0047] When the spacer 600 is inserted between adjacent spinous process, only the top and bottom portions 616, 618 of the spacer 600 will directly contact each spinous process. Therefore, the first outer shell 602 and the second outer shell 603 prevent direct 10 contact between the silicone and the spinous process. Accordingly, the spacer 600 helps prevent wear debris from being formed.

[0048] Now referring to Figure 7, still yet another embodiment of the present invention is spacer 700. Spacer 700 includes preferably a component in the shape of an elliptical or oval or cylindrical spool 710. Alternatively, the component 700 can be formed for method or suitable plastic material or composites including, by way of example only, 15 fibers for strength. The spacer 700 has a center shaft 702 with a bore 708 extending through . As in other embodiments the bore 708 can be, by way of example only, circular, oval or elliptical. A first end 704 and a second end 706 are integrally formed with the center shaft 702 in this preferred embodiment. Both the first end 704 and the second end 706 20 extend outward from the center shaft 702 and form a circular rim around each end of the center shaft 702. It is within the scope of the present invention for the first end 704 and

second end **706** to comprise other shapes such as, but not limited to, elliptical, circular, oval or egg-shaped.

5 [0049] A compressible medium **712** surrounds the center shaft **702**. As previously mentioned, the compressible substance is preferably silicone. The silicone extends out from the center shaft **702** until it is flush with the outer rim of both the first end **704** and the second end **706**. With the silicone around the center shaft **702**, the spacer **700** will look like an elliptical cylinder in this embodiment. The spacer **700** does not have an outer shell surrounding the silicone. When the spacer **700** is inserted between adjacent spinous process, the silicone will directly contact the spinous process. A preferred embodiment of the spacer **700** will have silicone with a graduated stiffness to help distribute the load placed upon the spacer **700**. For example, the hardness of the silicone can be the lowest at the outermost surface that contacts the spinous process, and the hardness of the silicone can be the highest where the silicone surrounds and contacts the center shaft **702**. Alternatively the hardness can be greater where the silicone contacts the spinous process and then less hard adjacent to the center shaft **702**.

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[0050] Now turning to Figure 8a, another embodiment of the present invention is spacer **800**. The spacer **800** has an outer shell **802** which can be metallic or plastic. The outer shell **802** is preferably elliptical in shape. It is within the scope of the present invention that the outer shell **802** can be a shape such as, but not limited to, a cylindrical or egg shape. Regardless of the shape, the outer shell **802** is open on both ends **808, 810**.

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[0051] A compressible substance **804** is placed within the outer shell **802** and is flush with both ends **808, 810** of the outer shell **802**. A bore **806** extends through the compressible substance **804**. If desired the bore can be defined by a metallic or plastic sleeve held on the compressible substance **804**. Similar to the previous embodiments, the compressible substance **804** is preferably silicone. A preferred embodiment of the spacer **800** has silicone with a graduated stiffness. In an embodiment, the hardness of the silicone can be the highest at the bore **806**, and the hardness of the silicone can be the lowest where the silicone contacts the inner surface of the outer shell **802**. Alternatively, the hardness of the silicone can be the highest adjacent shell and lowest about bore **806**.

[0052] When the spacer **800** is inserted between adjacent spinous processes, only the top and bottom portions **812, 814** will directly contact each spinous process. Therefore, the outer shell **802** prevents direct contact between the silicone and the spinous processes. Accordingly, the spacer **800** helps prevent wear debris from being formed.

[0053] By way of example only, the thickness of the outer shell can be about 0.010 inches with the hardness of the compressible medium being about 50 durometer. By way of example only, the outer shell can be about 0.010 inches with the hardness of the compressible medium being about 70 durometer.

[0054] It is also to be understood that the spacer **800** can include any of the compressible medium **804** discussed herein and/or compatible with the body, with a bore hole provided therethrough. That is to say that the outer shell **802** can be eliminated in this embodiment. Preferably the spacer is comprised of silicone, however, other materials are

within the spirit and scope of the invention. Fig. 8b depicts an egg-shaped spacer 800' with a bore 809'. The spacer 800' is comprised of a compressible medium.

[0055] Referring now to Figs. 9a-9b, the interspinous process device on implant 900 has a first support 902 and a second support 904. The first support 902 and the second support 904 directly contact the spinous process and can be made of a suitable metal or a suitable plastic. Both the first support 902 and the second support 904 have a contour 903. The contour 903 allows the device 900 to be contoured to and to engage each spinous process so, preferably, that the device 900 does not move laterally. Each contour 903 includes a concave portion 920 and upstanding ridges 922, 924. It is to be understood that the ridges can be higher than shown in Fig. 9a in order to define a deeper contour. Additionally, ridges 924, especially when higher, of supports 903, 904 together can define a first wing and ridges 922, especially when higher, of support 903, 904 define a second wing. Such wings can function in much the same way as the wings described in other embodiments of the invention.

[0056] During the method of implanting device 900, both spinous processes are exposed using appropriate surgical techniques, and thereafter the device 900 is positioned so that the saddles 903 of both the first support 902 and the second support 904 engage the respective spinous process. The concave shape of the saddle 903 distributes the forces between the saddle 903 and the respective spinous process. This ensures that the bone is not reabsorbed due to the placement of the device 900 and that the structural integrity of the bone is maintained.

5 [0057] Referring now to Figure 9b, the first support 902 has a female receiving mechanism 906 and the second support 904 has a male engaging mechanism 908. The width of the female receiving mechanism 906 and the male engaging mechanism 908 are substantially similar. The female receiving mechanism 906 further has an alignment column 905 to assist in the movement of the supports 902, 904 relative to each other.

10 [0058] The first support 902 and the second support 904 are interlocked so that the first support 902 and the second support 904 cannot be independently separated. The first support 902 has a ledge 907 that extends around the inner circumference of the first support 902. Similarly, the second support 904 has a ledge 909 extending around the circumference of the male engaging mechanism 908. If the first support 902 and the second support 904 travel in opposite directions, the ledges 907 and 909 will eventually engage and prevent the first support 902 and the second support 904 from separating. Preventing the first support 902 and the second support 904 from separating also contains the compressible medium 910, as described below, within the device 900.

15 [0059] Placed within the female receiving mechanism 906 is a compressible medium 910. As previously mentioned, the compressible medium 910 provides resistance, limiting the possible range of motion of the spinous process. By way of example only, the compressible medium 910 can be silicone. It is within the scope of the present invention that the compressible medium can include, by way of example only, a spring mechanism, a synthetic gel or a hydrogel. The compressible or deformable material can also include material which offers, for example, increased resistance to compression the more the

material is compressed. For example, as compression and deformation occur, the material can offer a steady resistive force or a resistance force that increases, either linearly or non-linearly, the more the implant is compressed.

[0060] With respect to an embodiment with a graduated stiffness, the hardness of the silicone can be the lowest where the first support **902** contacts the silicone, and the hardness of the silicone **910** can be the highest where the second support **904** contacts the silicone. Alternatively, the silicone can have a higher hardness in the center of the silicone riding between the supports **902, 904**.

[0061] In this and with the other embodiments, the medium **910** can also be designed to vary resistance to movement according to the speed or rate of deformation. For example, when an individual leans back slowly, the adjacent spinous processes place a force onto the first support **902** and the second support **904**. With slow backward bending the force is small and gradual until the limit of compression of the material is reached. However, if the individual attempts a rapid activity that can result in a severe first compression of the device **900**, the medium **910** can offer higher stiffness, preventing the spinous processes from making excessive motion and causing pain.

[0062] Preferably, the height of the device **900** is slightly larger than the undistracted distance between the adjacent spinous processes. When the device **900** is then inserted between the spinous process, the contours **903** will press against each spinous process and assist to keep the device **900** in place. During a daily routine, an individual will perform functions that will translate into vertical movement of each spinous process. It is important

that the individual be able to retain some of his normal range of motion. To retain a normal range of motion, the device 900 can preferably be compressed when the spinous processes place a force upon the first support 902 and the second support 904. Thus, when the device 900 is in a normal state the outer peripheral edge 930, 932 of first and second support 902, 5 904 respectively do not contact each other. However, ridges 930, 932 act as a limit to the amount device 900 can be compressed. Such an arrangement reduces potential resorption of the bone adjacent to the implant and to more gradually limit extension or backward bending of the spinal column.

10 [0063] The embodiment of this implant as well as the several other implants described herein act to limit extension. These implants, however, do not inhibit the flexion of the spinal column when the spinal column is bent forward.

15 [0064] The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following 20 claims and their equivalence.